

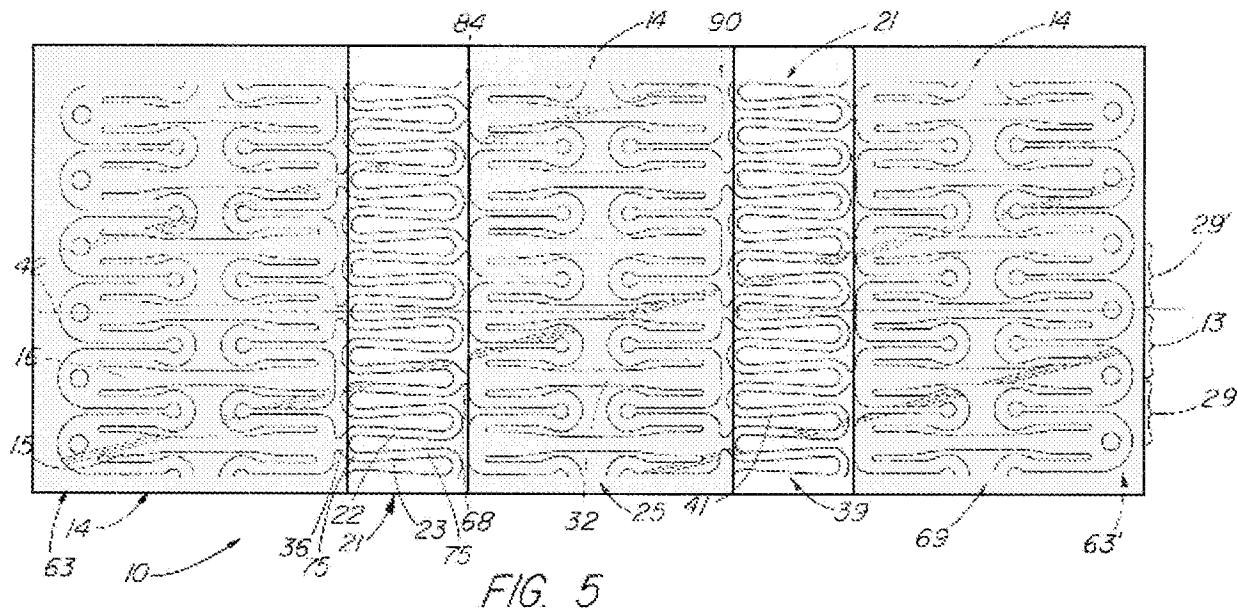
REMARKS

Claims 52 and 54-55, 57-64 are currently pending.

Claims 52, 54, and 57 have been amended. Claim 56 has been canceled. Claim 64 is new. Claims 52 and 57 have been amended to recite that the even and odd circumferential bands are exclusively connected by flexible connectors. Support for these amendments can be found throughout the specification, for example pages 10 and 12, as well as Fig. 7. Claims 52 has been amended to recite that the even and odd circumferential bands each form single continuous sinusoidal bands. Support for these amendments can be found throughout the specification, for example page 6, as well as Figs. 3 and 7. Claims 52, 54, 55, and 57 have been amended further to recite that the flexible connectors or third loop containing sections join the adjacent circumferential bands or first and second loop containing sections at longitudinally offset loops of said bands or loop containing sections. Support for these amendments can be found throughout the specification, for example pages 8-9 as well as Figs. 4 and 7. Claim 64 recites a stent according to claim 52 wherein the cells have a non-uniform pattern of cells. Support for this claim can be found throughout the specification, for example page 12 as well as Fig. 7. No new matter is introduced by these amendments. Applicant reserves the right to prosecute the subject matter of the cancelled claims in one or more continuation, continuation-in-part, or divisional applications.

Response to Rejection Under 35 U.S.C. §102(e) / 35 U.S.C. §103(a) Based on Berry

Claims 52, 54-57 and 62-63 have been rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berry et al. (6,231,598). To support the rejection, the Examiner has identified Figure 5 of Berry, wherein the Examiner asserts that sections 14, 25 and 69 (in yellow below) allegedly form substantially single continuous sinusoidal bands and sections 21 and 39 (shown in pink below) allegedly show “either continuous or non-continuous” loop containing sections “depending on a reference frame.”



Applicants respectfully disagree with this rejection. All of the pending claims contain one or more distinguishing features not taught or suggested by Berry.

Claims 52, 54-55, 57 and 62-63 are not anticipated by Berry

Berry does not teach or suggest adjacent odd and even circumferential bands, each forming single continuous generally sinusoidal bands that are connected exclusively by a plurality of flexible connectors. Berry also does not teach or suggest first and second loop containing sections, each forming a single continuous sinusoidal band that are joined together exclusively through a third loop containing section.

First, Claims 52 and 57 each require an odd circumferential band containing a pattern of loops that are out of phase with the loops of the even circumferential bands. The even and odd circumferential bands or first and second loop containing sections as *identified by the Examiner* in Berry, as highlighted in boxes below, fail to teach a pattern of loops which are out of phase with one another.

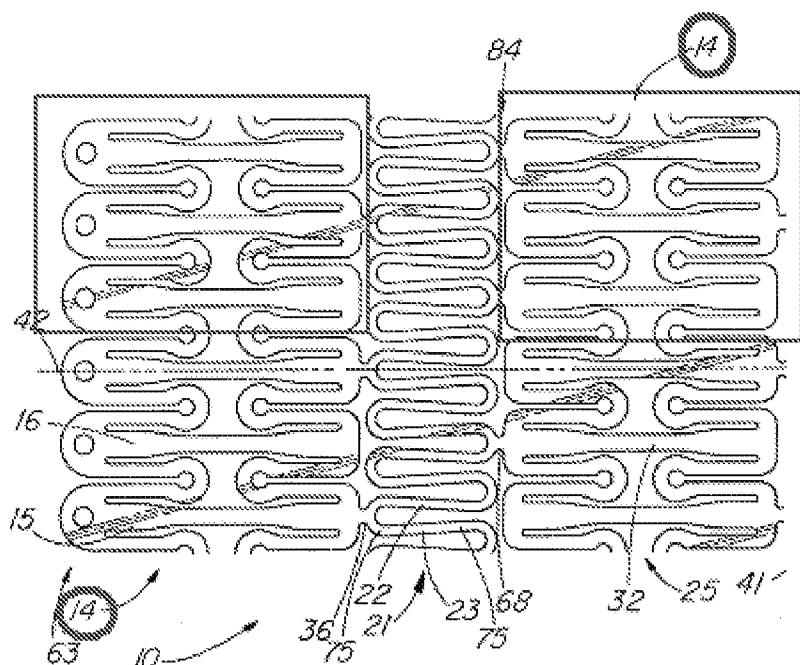


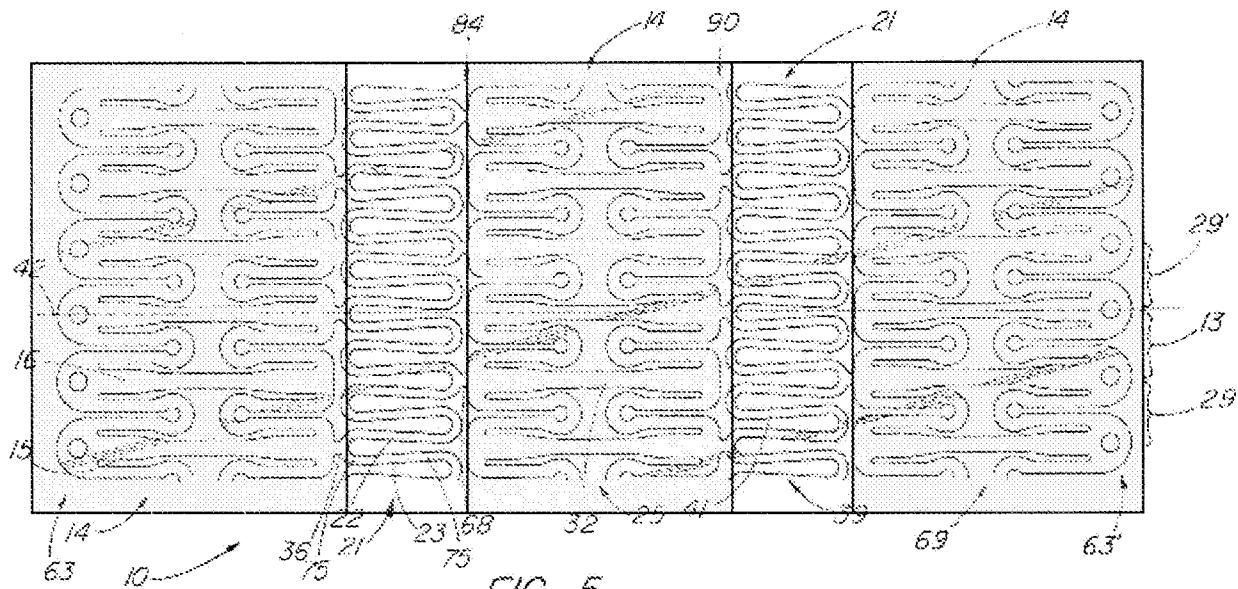
FIG. 5

Each longitudinal segment (14; see also 25 and 69) is structurally the same, and therefore as Fig. 5 of Berry illustrates, the loops of adjacent longitudinal segments are in identical alignment.

Therefore, the Examiner's identification of the entire Berry longitudinal segment (14) as both an odd circumferential band and an even circumferential band is, respectfully, incorrect. The same structure (14) necessarily cannot be out of phase with itself.

Second, claims 52, 54, and 57 also require that the "circumferential bands each form single continuous sinusoidal bands." Claim 55 similarly requires that the first and second loop containing sections each form single continuous sinusoidal bands.

On page 2 of the Office Action the Examiner identifies in Fig. 5 of Berry 1st and 2nd loop containing sections (highlighted in yellow below) and 3rd loop containing sections (highlighted in pink below) - which are the same structures identified as odd, even and loop containing flexible members, respectfully, and states that these structures form substantially single continuous sinusoidal bands.



Applicant respectfully disagrees. Sinusoids are described in the instant specification as a pattern consisting of "two loops 304 and 306 per period wherein loops 304 open to the right while loops 306 open to the left" such that "member 308 joins one loop 304 to its following loop 306 and member [310] joins one loop 306 to its following loop 304" (page 11, lines 18-24). This arrangement results in a single, continuous undulating band as illustrated by Fig. 3 of the instant application as follows:

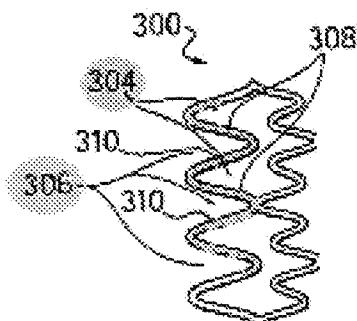
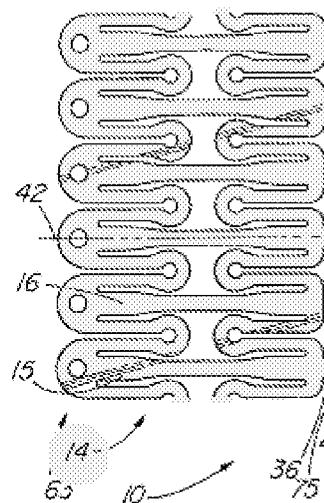
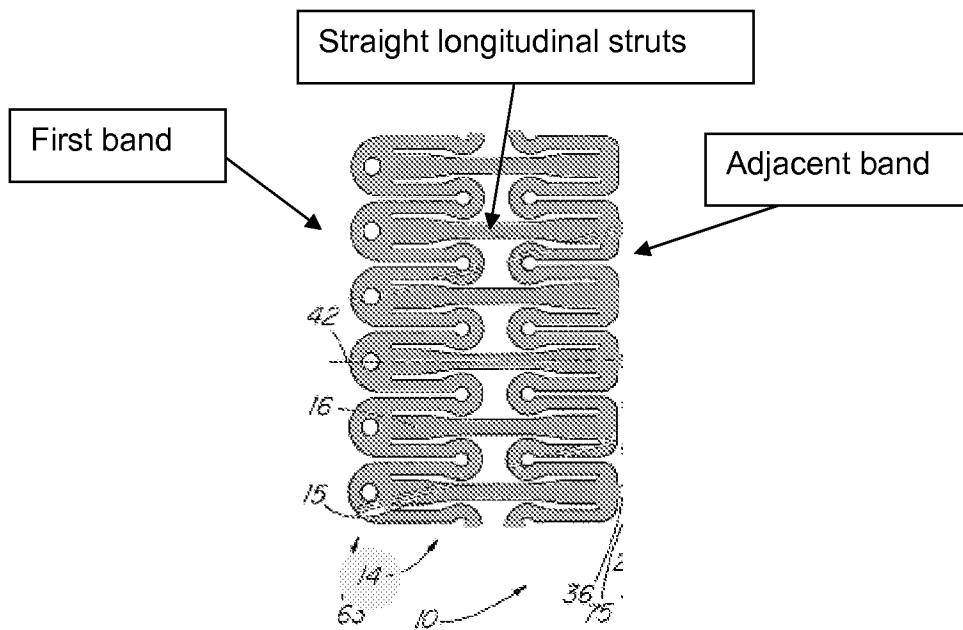


FIG. 3

By contrast, the Examiner-identified structure (14) in Berry does not form a single continuous sinusoidal band:



As shown above, Fig. 5 shows the stent depicted in Fig. 1 “cut longitudinally and unrolled into a single plane.” Berry, col. 6, ll. 50-51. In this view, no *single* continuous sinusoidal band is evident in structure (14). Even rolled (as shown in Fig. 1), structure (14) is not a *single* continuous sinusoidal band, and, respectfully, the Examiner has not shown how it could be. Rather, structure (14) contains multiple bands connected together by longitudinal struts.



Specifically, if the top part of Fig. 5 is connected to the bottom part of Fig. 5, the left portion of structure (14) connects to itself but does not connect to the right portion of structure (14) – and vice versa – except by way of longitudinal struts (15, 16, 32), which fall outside the scope of a *single* sinusoidal band. Berry, col. 9, ll. 25-30. For the same reason, structure (14) cannot be a circumferential band that forms a *single* continuous sinusoidal band because it contains multiple bands connected by a straight longitudinal strut. For at least this additional reason, Berry does not anticipate claims 53, 54-57 and 62-63.

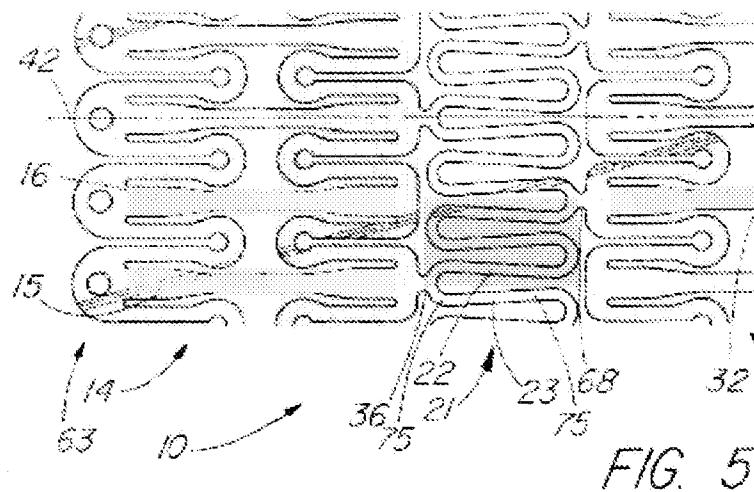
This, Claims 52 and 57 further require “an odd circumferential band occurring between every two even [first] circumferential bands” and “a plurality of loop containing flexible connectors connecting adjacent even and odd circumferential bands,” wherein “even and odd circumferential members are connected exclusively by said flexible connectors”. Thus, the stents of claims 52 and 57 have alternating odd and

even circumferential bands that are connected exclusively by flexible connectors, not directly to each other or through straight or rigid connectors.

Similarly, independent claim 55 and dependent claims 62-63 require a “third loop containing section disposed in the generally circumferential space between said first and second loop containing sections such that each said first and second loop containing sections are joined together through the third loop containing section ... without other connection directly between the first and second loop containing sections”. Thus, the stent of claim 55 has first and second loop containing sections that are joined together exclusively through third loop containing sections, not directly to each other or through straight or rigid connectors as depicted in Figure 5 of Berry above.

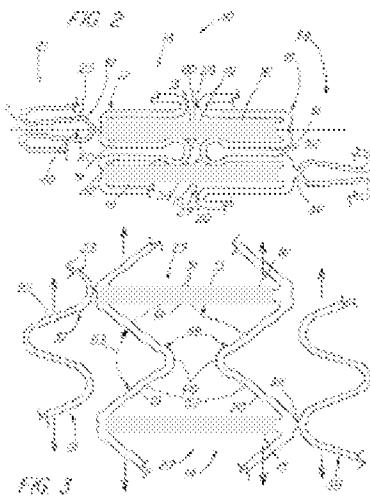
Contrary to the Examiner’s assessment of Berry, the longitudinal segment identified by the Examiner, for example section (14), does not have odd and even loop containing circumferential bands connected exclusively by flexible connectors, nor does section (14) have 1st and 2nd loop containing sections that are connected exclusively by a 3rd loop containing section. Berry describes section (14) as a series of longitudinal struts (32; see also 15, 16) that are interconnected by a series of adjustable members (19, 20). Berry, col. 9, ll. 25-39. At best, section 14 (and 25, 69) is a series of bends which are connected by straight longitudinal struts.

As illustrated below, each half of the pair of the “bands” (green, blue) is connected to another half of a pair of “bands” by either a longitudinal strut (15, 16; yellow) or one of a series of “undulating bends” (75; pink) of a “flexible interconnection segment” (22).



Thus, the only structures of Berry Fig. 5 that could be the “single continuous sinusoidal bands,” are not exclusively connected to one another by “loop containing flexible connectors” or “3rd loop containing sections”.

Further, because the longitudinal struts (32; 15, 16) are straight (*i.e.*, non-loop-containing), they are fixed connectors rather than flexible connectors. A comparison of Figs. 2 and 3 of Berry shows that longitudinal struts (15, 16) fix the relative longitudinal distance between each half of the pair during expansion, as illustrated below (yellow).



Therefore, the longitudinal struts do not qualify as flexible connectors, as claimed.

Finally, with respect to claim 55, applicants do not understand the Examiner's conclusion that "each 3rd loop containing section is non-continuous because there are many 3rd loop containing sections, each .. limited within a cell". Claim 55 is directed to a stent, not to a cell. The stent of claim 55 comprises a plurality of first, second and third loop containing sections that respectively form bands, the bands forming a stent. The first and second loop containing sections each form bands that are single continuous sinusoidal bands. The third loop containing sections also form bands, at least one of which is a single continuous generally sinusoidal band as illustrated in Fig. 7 of the instant application. Specifically, Claim 55 recites that "the third loop containing sections form a plurality of bands, at least one of said bands consisting of a single continuous sinusoidal band." Significantly, it is the band that is continuous or non-continuous, not the third loop containing sections.

Accordingly, for at least the reasons set forth above, Berry does not anticipate any of claims 52, 54-55, 57 and 62-63.

Claims 52, 54--55, 57 and 62-63 are not obvious over Berry

The Examiner further states that it would have been obvious to one of ordinary skill in the art to configure the bands of the stent taught by Berry in a sinusoidal configuration. Applicant respectfully disagrees. Berry does not render any of claims 52, 54-55, 57 and 62-63 obvious, because nothing in Berry suggests to the person of ordinary skill in the art to modify the Berry stent so that the halves of the longitudinal segment (14) could be exclusively connected by a plurality of flexible connectors or third loop containing sections. Indeed, Berry explicitly teaches away from reconfiguring the longitudinal struts (32) or reconfiguring entire longitudinal segments (14) into sinusoidal bands. As noted above, the Berry longitudinal struts (e.g., 32, 15 or 16 in the illustration above on page 9) are designed to remain parallel to the longitudinal axis of the stent upon expansion and provide longitudinal stiffness to the Berry stent. The effect of this design is to render the entire longitudinal segment (14, 25 or 69) stable and fixed in the longitudinal direction during expansion. Berry, col. 9, ll. 24-27. Therefore, one of ordinary skill in the art would not reconfigure the Berry longitudinal segments so as to comprise single continuous sinusoidal bands that do not include a straight longitudinal component. For at least these reasons, claims 52, 54-55, 57 and 62-63 are not obvious over Berry.

Further, the longitudinal flexibility of either the claimed flexible connectors or third loop containing sections contributes to the overall flexibility of the stent as defined by the instant application under “Field of Invention.” The Berry stent does not have overall flexibility, it is an articulated stent. Berry explicitly teaches that the longitudinal segments (14) are inflexible, such that longitudinal flexibility is provided

solely by the flexible interconnection segments (shown in pink above, page 9) that otherwise connect adjacent longitudinal segments (shown in yellow above, page 9). See Berry col. 10, ll. 26-32. Moreover, one skilled in the art would not be motivated to modify the structure of the longitudinal segment, because the common sense way to alter the flexibility of the Berry stent would be to follow the teachings of Berry. Berry teaches that flexibility may be adjusted by varying the number of interconnection points, *i.e.*, the number of struts that connect the interconnection segment (21) to the longitudinal segment (14). Berry, col. 11, ll. 51-54. However, even removing the interconnection points would not remove the stiffness imposed by the straight longitudinal struts in Berry. Nor would it lead to the claimed invention.

Finally, Berry teaches away from modifying the longitudinal struts to flexible or loop containing sections, because the radial stiffness of the longitudinal sections is taught as advantageous. See Berry col. 3, l. 5 – col. 4, l. 27.

For at least the reasons set forth above, claims 52 and 54-55, 57 and 62-63 are not obvious over Berry.

Applicants respectfully request reconsideration and withdrawal of the §102(e) and alternative §103(a) rejections.

Response to Rejection Under 35 U.S.C. §103(a) Based on Berry in View of Roubin

Claims 58-61 have been rejected under 35 U.S.C. §103(a) as unpatentable over Berry et al. (6,231,598) in view of Roubin (5,827,321). Applicants respectfully disagree with and traverse this rejection.

The Examiner has stated that Roubin supplies the missing element of Berry of omitting flexible connectors to form bigger cells. First, applicants respectfully disagree that one skilled in the art would look to Roubin to omit flexible connectors in Berry to provide various flexibility as suggested in Roubin. Second, applicants respectfully disagree that this is the only deficiency of Berry and, therefore, even if the skilled artisan were to remove connectors in Berry as suggested in Roubin one would not arrive at the invention of claims 58-61.

One skilled in the art would not look to Roubin to omit interconnection segments of the Berry stent. As the Examiner has recognized, Berry does not achieve stent flexibility by eliminating portions of the interconnection segments. As explained above, Berry teaches that flexibility may be adjusted by increasing or decreasing the number of interconnection points joining the longitudinal and interconnection segments, compare Figs. 5 and 8. Berry, col. 11, ll. 51-55; col. 12, ll. 4-11. This increases the articulation angle of the stent, it does not affect overall flexibility of the stent. Unlike Berry, Roubin is not an articulated stent. Because Berry achieves “flexibility” by a different means than Roubin, one skilled in the art would not look to the earlier Roubin to modify the later Berry.

The deficiencies of Berry exceed merely not teaching omission of interconnection segments as discussed above in detail. Roubin does not remedy all of the deficiencies of Berry. Like Berry, Roubin does not teach or suggest cells formed of adjacent even and odd circumferential bands and flexible connectors, wherein a square cell is arranged amongst a plurality of triangular cells. Roubin also fails to teach or suggest the stent of independent claim 57, wherein even and odd circumferential bands

are connected exclusively by flexible connectors at longitudinally offset loops. Indeed, to the extent cells may be defined in the Roubin Fig. 9 stent, identified by the Examiner, none is formed of adjacent even and odd circumferential bands and flexible connectors that exclusively connect the even and odd circumferential bands at longitudinally offset loops, as required in claim 57. One skilled in the art would not arrive at the square and triangular cells of claim 57 by reading Berry in view of Roubin.

The flexible connectors of claim 57 (and claims 58-61) connect adjacent even and odd circumferential bands at offset loops, unlike either Berry or Roubin. These connections are illustrated by elected Fig. 7 of the instant application and described in the specification as follows:

Longitudinally offset loops of circumferential bands connected by flexible connectors

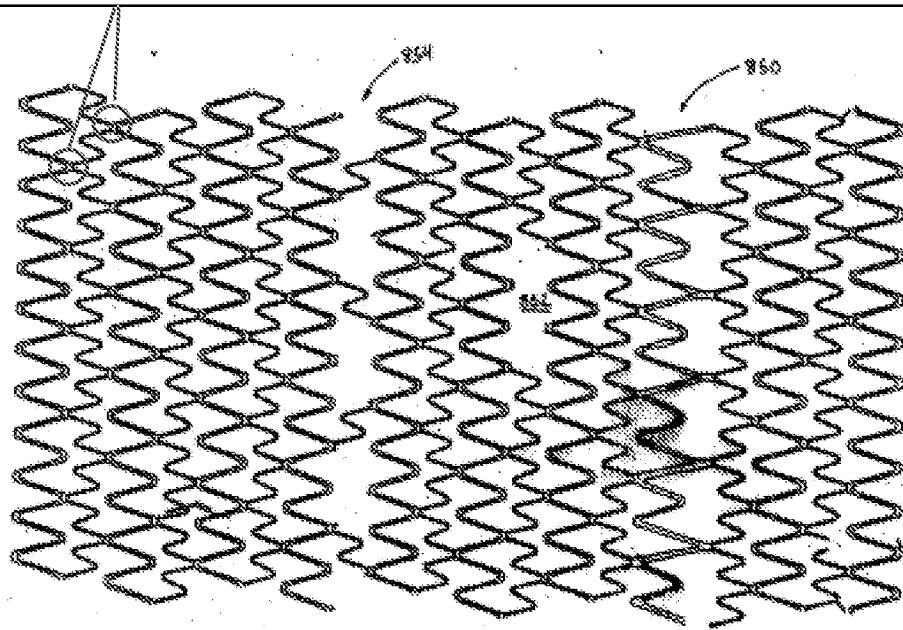
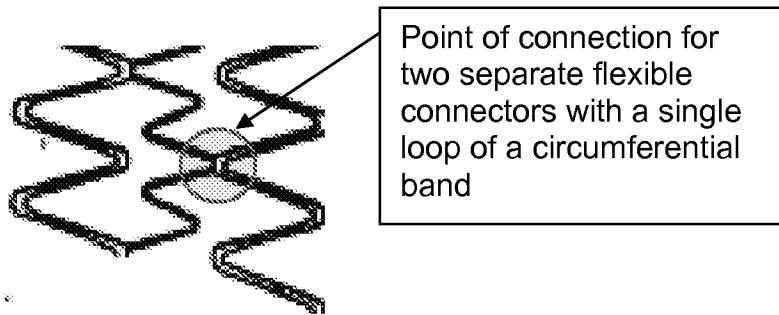
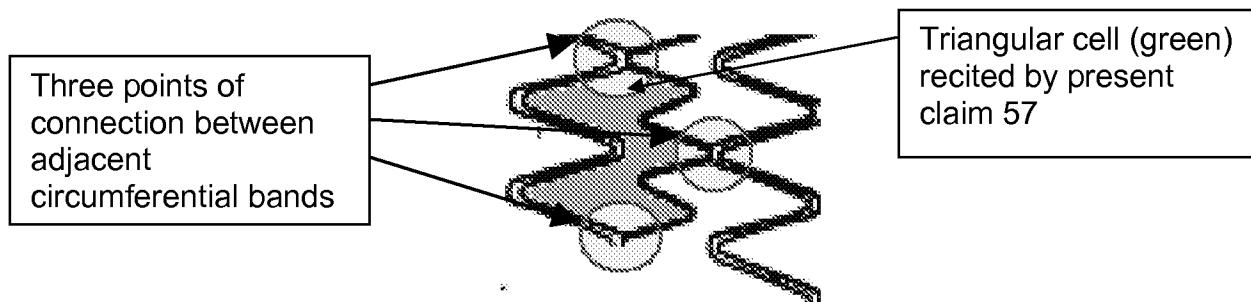


FIG. 7

By connecting longitudinally offset loops, the flexible connectors may be arranged such that two separate flexible connectors may join a single loop of a circumferential band as illustrated below:



This arrangement in turn enables the formation of triangular cells, as recited by claim 57. A cell is "triangular" when, there are only three points of connection between adjacent circumferential bands or between adjacent first and second loop containing sections.



By contrast, the "connecting members" taught by Roubin Fig. 9, as cited by the Examiner, connect longitudinally adjacent apices of adjacent "annular elements":

Longitudinally adjacent loops of annular elements connected by “connecting members”

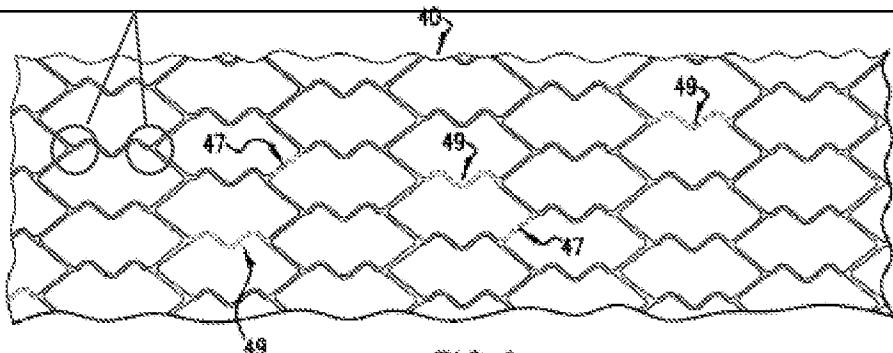


FIG.9

As the illustration shows, Roubin does not teach cells formed by three points of connection between adjacent annular elements. As a result of this configuration, Roubin cannot meet the limitation of claim 57 that the flexible connectors and adjacent even and odd circumferential bands form cells “wherein a square cell is arranged amongst a plurality of triangular cells.” Roubin does not teach or suggest how to reconfigure the annular elements or connecting members to achieve a triangular cell. Similarly, Berry does not teach or suggest how to reconfigure the longitudinal segments, longitudinal struts, interconnection segments, interconnection struts, or interconnected curvilinear struts to make cells formed of flexible members and even and odd circumferential bands to create a plurality of triangular cells (with or without square cells arranged amongst them).

Finally, because Roubin does not teach or suggest square cells formed out of flexible connectors connecting adjacent circumferential bands at longitudinally offset loops, either in-phase or out-of-phase, as required by claims 58-60, or square cells in which adjacent circumferential bands have a different numbers of loops, as required by dependent claim 61, Roubin cannot supply these deficiencies of Berry. No combination of Roubin and Berry leads the skilled artisan to claims 58-61.

For at least the reasons set forth above, claims 58-61 are not obvious over Berry in view of Roubin. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) as to the present Claims 58-61 are respectfully requested.

CONCLUSION

Based on the foregoing amendments and remarks, applicant respectfully requests reconsideration and withdrawal of the rejections of the pending claims and requests allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-4387**, Order No. 92077.003US8.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-4387**, Order No. 92077.003US8.

Respectfully submitted,
Cadwalader, Wickersham & Taft LLP

By: _____
Karen J. Axt
Registration No. 63483

Address:
Cadwalader, Wickersham & Taft LLP
One World Financial Center
New York, NY 10281
(212) 504-6465 Telephone
(212) 504-6666 Facsimile